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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,576	05/03/2005	John Robert Duchek	1575 WO/US	2302
7590 Jeffrey S Boone Mallinckrodt 675 McDonnell Boulevard P O Box 5804 St Louis, MO 63134			EXAMINER DENTZ, BERNARD I	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 12/20/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,576	<b>Applicant(s)</b> DUCHEK, JOHN ROBERT	
	<b>Examiner</b> Bernard Dentz	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8-15 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5, 8-15 and 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Process claims 3-5,8-15 and 18-21 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Fahrenholtz for essentially the reasons of record.

It teaches the purification of a cannabinoid by esterifying with an aryl sulfonyl halide in the presence of a base, i.e. pyridine, followed by several washing steps, a drying step and evaporation to form a residue, followed by repeated recrystallization from methanol. The product is crystalline and stable at room temperature.

It is then hydrolyzed to recover the cannabinoid. See Ex. 12.

This meets applicant's process claims with the exception of the use of pyridine instead of a trialkyl amine as the basic catalyst in the esterification of the cannabinoid. However the interchangeability of these basic substances is well known in the art.

Note that applicants use methanol as one of the crystallization solvents. See claim 12.

Compound claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahn. Although applicants have removed the possibility of ring A being benzene and thus removed the anticipation rejection over Cahn, the obviousness rejection still pertains. The statement in the previous rejection that the instant aryl sulfonates of cannabinol type compounds are obvious in view of Cahn's crystalline compounds was and is meant to include the dihydro, tetrahydro and hexahydrocannabinols.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahrenholtz et al. In view of its teaching of the synthesis of the crystalline meta-nitrobenzene sulfonate of delta-9-THC in the separation of delta-9-THC from delta-8 THC it would have been obvious to make other common benzenesulfonate esters, e.g. the benzene- or alkylbenzene- or halobenzene-sulfonate esters in the purification of

impure cannabinoids. Note from the preamble of claim 1 that applicant uses "cannabinoid" to refer to the hydrocannabinols as well as non-hydrocannabinols.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahrenholtz et al in view of Cahn. It is clearly suggested to one of ordinary skill in the art from the above explanation of Fahrenholtz et al and the making of the benzene- and m-nitrobenzene sulfonates of non-hydro-cannabinoids by Cahn to make the instant cannabinoid benzene sulfonate esters.

Claims 3-5 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda et al, cited by applicants. It discloses a process reading on claim 3 except that a mixture of  $\text{NaCO}_3$  and  $\text{NaHSO}_3$  is used as the base. The 4-dimethylaminoazobenzene-4'-sulfonate derivatives are made which are crystalline and stable at room temperature under air.

Applicant's arguments filed 9-20-2007 have been fully considered but they are not persuasive. Applicants arguments concerning the higher yields obtained in their recrystallization process are not probative. The Fahrenholtz process uses repeated recrystallization from methanol to obtain a 23% yield of purer product.

The Cahn et al anticipation rejection has been overcome by the narrowing of claim 1. The rejection over Melikian et al is overcome because of the recitation of that the cannabinoid aryl sulfonates are crystalline and stable at room temperature under air. Melikian et al's process produces dimethylamino-naphthalenyl sulfonates which are unstable on exposure to air. See last par. of the article.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dentz

BERNARD DENTZ  
PRIMARY EXAMINER

12-17-2007